

FY 01**Total BPD Reports**

	NUMBER OF REPORTING ESTABLISHMENTS	TOTAL REPORTS RECEIVED	<i>POTENTIAL RECALLS</i>	
BLOOD/PLASMA MANUFACTURERS				
LICENSED BLOOD ESTABLISHMENTS	376/*123	19398	1406	7.2%
UNLICENSED BLOOD ESTABLISHMENTS	247	1039	22	2.1%
TRANSFUSION SERVICES	277	519	0	0.0%
PLASMA CENTERS	345/*44	4013	242	6.0%
<i>SUB-TOTAL</i>	1245	24969	1670	6.7%
NON-BLOOD MANUFACTURERS				
ALLERGENICS MANUFACTURER	9	243	13	5.3%
BLOOD DERIVATIVE MANUFACTURER	15	56	4	7.1%
IN-VITRO DIAGNOSTIC MANUFACTURER	9	28	18	64.3%
THERAPEUTIC MANUFACTURER	11	19	7	36.8%
VACCINE MANUFACTURER	11	52	1	1.9%
<i>SUB-TOTAL</i>	55	398	43	10.8%
TOTAL	1300	25367	1713	6.8%

*Number of license holders; may be one or more establishments operating under one license.

FY 01**Reportable vs Non-Reportable BPDs**

	Total Reports Received	Reportable	% Reportable	Non- Reportable	% Non- Reportable
BLOOD/PLASMA MANUFACTURERS					
LICENSED BLOOD ESTABLISHMENTS	19398	18554	95.6%	844	4.4%
UNLICENSED BLOOD ESTABLISHMENTS	1039	976	93.9%	63	6.1%
TRANSFUSION SERVICES	519	476	91.7%	43	8.3%
PLASMA CENTERS	4013	3833	95.5%	180	4.5%
<i>SUB-TOTAL</i>	24969	23839	95.5%	1130	4.5%
NON-BLOOD MANUFACTURERS					
ALLERGENICS MANUFACTURER	243	224	92.2%	19	7.8%
BLOOD DERIVATIVE MANUFACTURER	56	56	100.0%	0	0.0%
IN-VITRO DIAGNOSTIC MANUFACTURER	28	27	96.4%	1	3.6%
THERAPEUTIC MANUFACTURER	19	17	89.5%	2	10.5%
VACCINE MANUFACTURER	52	51	98.1%	1	1.9%
<i>SUB-TOTAL</i>	398	375	94.2%	23	5.8%
TOTAL	25367	24215	95.5%	1153	4.5%

FY 00 vs FY 01

Total BPD Reports

	#Reporting Establishments		Total Reports		Potential Recall	
	FY-00	FY-01	FY-00	FY-01	FY-00	FY-01
BLOOD/PLASMA MANUFACTURERS						
LICENSED BLOOD ESTABLISHMENTS	402/*122	376/*123	20196	19398	1184	1406
UNLICENSED BLOOD ESTABLISHMENTS	53	247	125	1039	11	22
TRANSFUSION SERVICES	10	277	53	519	2	0
PLASMA CENTERS	316/*48	345/*44	2972	4013	179	242
<i>SUB-TOTAL</i>	781	1245	23346	24969	1376	1670
NON-BLOOD MANUFACTURERS						
ALLERGENIC	6	9	57	243	6	13
DERIVATIVE	15	15	34	56	3	4
IN-VITRO DIAGNOSTIC	11	9	38	28	7	18
THERAPEUTIC	14	11	32	19	5	7
VACCINE	8	11	21	52	4	1
<i>SUB-TOTAL</i>	54	55	182	398	25	43
TOTAL	835	1300	23528	25367	1401	1713

*Number of license holders; may be one establishment or multiple establishments operating under one license.

FY 00 vs FY 01

Reportable vs Non-Reportable BPDs

	Total		Reportable		Non-Reportable	
	FY-00	FY-01	FY-00	FY-01	FY-00	FY-01
BLOOD/PLASMA MANUFACTURERS						
LICENSED BLOOD ESTABLISHMENTS	20196	19398	19680	18554	516	844
UNLICENSED BLOOD ESTABLISHMENTS	125	1039	109	976	16	63
TRANSFUSION SERVICES	53	519	36	476	17	43
PLASMA CENTERS	2972	4013	2891	3833	81	180
<i>SUB-TOTAL</i>	23346	24969	22716	23839	630	1130
NON-BLOOD MANUFACTURERS						
ALLERGENIC	57	243	50	224	7	19
DERIVATIVE	34	56	31	56	3	0
IN-VITRO DIAGNOSTIC	38	28	35	27	3	1
THERAPEUTIC	32	19	32	17	0	2
VACCINE	21	52	20	51	1	1
<i>SUB-TOTAL</i>	182	398	168	375	14	23
TOTAL	23528	25367	22884	24214	644	1153

FY 00 vs FY 01

Reportable Blood & Plasma BPDs By Manufacturing System

MANUFACTURING SYSTEM	FY-00		FY-01	
<i>DONOR SUITABILITY</i>	19614	86.3%	19556	82.1%
POST DONATION INFORMATION	18471	81.3%	18256	76.6%
DONOR SCREENING	1070	4.7%	1210	5.1%
DONOR DEFERRAL	73	0.3%	90	0.4%
<i>QC & DISTRIBUTION</i>	1508	6.6%	1892	7.9%
<i>LABELING</i>	908	4.0%	1313	5.5%
<i>PRODUCT TESTING</i>	389	1.7%	624	2.6%
ROUTINE TESTING	310	1.4%	542	2.3%
VIRAL TESTING	79	0.3%	82	0.3%
<i>COMPONENT PREPARATION</i>	165	0.7%	264	1.1%
<i>COLLECTION</i>	127	0.6%	150	0.6%
<i>MISCELLANEOUS</i>	5	0.0%	40	0.2%
TOTAL	22716	100%	23839	100%

- For blood and plasma, post donation information (PDI) continues to be the most frequently reported event.
- The most common PDI involved donors providing information concerning:
FY-01: travel to malarial endemic areas.
FY-00: travel to the United Kingdom for a cumulative of 6 months or more from 1980 to 1996 (a potential risk for vCJD.)

FY 01 Post Donation Information (PDI) - How Obtained

PDI OBTAINED THROUGH:	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	PLASMA CENTERS	TOTAL	
SUBSEQUENT DONATION	13189	116	3059	16,364	89.6%
TELEPHONE CALL FROM DONOR	1086	9	20	1115	6.1%
THIRD PARTY (e.g., doctor, family)	361	1	415	777	4.3%
TOTAL	14636	126	3494	18,256	100%

THE PDI WAS:	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	PLASMA CENTERS	TOTAL	
KNOWN, BUT NOT PROVIDED AT TIME OF DONATION*	12,955	107	3359	16,421	89.9%
NOT KNOWN AT TIME OF DONATION**	1681	19	135	1835	10.1%
TOTAL	14,636	126	3494	18,256	100%

* known, e.g., travel outside of U.S., tattoo or body piercing, history of cancer

**not known, e.g., post donation illness, cancer diagnosed post donation, sex partner participated in high risk behavior or tested positive

FY 00 vs FY01

Blood & Plasma Non-Reportable BPDs By Manufacturing System

MANUFACTURING SYSTEM	FY-00		FY-01	
<i>MISCELLANEOUS</i>	303	48.1%	571	50.5%
<i>QC & DISTRIBUTION</i>	90	14.3%	349	30.9%
<i>DONOR SUITABILITY</i>	104	16.5%	116	10.3%
POST DONATION INFORMATION	40	6.3%	65	5.8%
DONOR SCREENING	59	9.4%	51	4.5%
DONOR DEFERRAL	5	0.8%	0	0.0%
<i>LABELING</i>	121	19.2%	86	7.6%
<i>COLLECTION</i>	8	1.3%	4	0.4%
<i>PRODUCT TESTING</i>	3	0.5%	2	0.2%
<i>COMPONENT PREPARATION</i>	1	0.2%	2	0.2%
TOTAL	630	100%	1130	100%

- Non-reportable BPDs increased by 44% in FY01 due to the revised reporting regulation. 282 miscellaneous reports involved product made available for distribution but not distributed which would have been reportable under the previous regulation.
- 247 QC & Distribution reports involved frozen products (e.g., Fresh Frozen Plasma) shipped to a hospital and broken or damaged during thawing. These products were unsuitable for transfusion and discarded. In FY 01, these events were deemed not reportable, as they are rarely identified as system problems in manufacturing and are generally tied to an unusual shipment event.